

Food and Drug Administration, HHS

§ 862.3

862.3200 Clinical toxicology calibrator.
862.3220 Carbon monoxide test system.
862.3240 Cholinesterase test system.
862.3250 Cocaine and cocaine metabolite test system.
862.3270 Codeine test system.
862.3280 Clinical toxicology control material.
862.3300 Digitoxin test system.
862.3320 Digoxin test system.
862.3350 Diphenylhydantoin test system.
862.3360 Drug metabolizing enzyme genotyping system.
862.3380 Ethosuximide test system.
862.3450 Gentamicin test system.
862.3520 Kanamycin test system.
862.3550 Lead test system.
862.3555 Lidocaine test system.
862.3560 Lithium test system.
862.3580 Lysergic acid diethylamide (LSD) test system.
862.3600 Mercury test system.
862.3610 Methamphetamine test system.
862.3620 Methadone test system.
862.3630 Methaqualone test system.
862.3640 Morphine test system.
862.3645 Neuroleptic drugs radioreceptor assay test system.
862.3650 Opiate test system.
862.3660 Phenobarbital test system.
862.3670 Phenothiazine test system.
862.3680 Primidone test system.
862.3700 Propoxyphene test system.
862.3750 Quinine test system.
862.3830 Salicylate test system.
862.3840 Sirolimus test system.
862.3850 Sulfonamide test system.
862.3870 Cannabinoid test system.
862.3880 Theophylline test system.
862.3900 Tobramycin test system.
862.3910 Tricyclic antidepressant drugs test system.
862.3950 Vancomycin test system.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 52 FR 16122, May 1, 1987, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 862 appear at 73 FR 35341, June 23, 2008.

Subpart A—General Provisions

§ 862.1 Scope.

(a) This part sets forth the classification of clinical chemistry and clinical toxicology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a pre-

market notification submission for a device under part 807 cannot show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required in § 807.87.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

(d) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

[52 FR 16122, May 1, 1987, as amended at 67 FR 58329, Sept. 16, 2002]

§ 862.2 Regulation of calibrators.

Many devices classified in this part are intended to be used with a calibrator. A calibrator has a reference value assigned to it which serves as the basis by which test results of patients are derived or calculated. The calibrator for a device may be (a) manufactured and distributed separately from the device with which it is intended to be used, (b) manufactured and distributed as one of several device components, such as in a kit of reagents, or (c) built-in as an integral part of the device. Because of the central role that a calibrator plays in the measurement process and the critical effect calibrators have on accuracy of test results, elsewhere in this part, all three of these types of calibrators (§§ 862.1150 and 862.3200 of this part) are classified into class II, notwithstanding the classification of the device with which it is intended to be used. Thus, a device and its calibrator may have different classifications, even if the calibrator is built into the device.

§ 862.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of